

1      **Claims 1 – 15 (cancelled)**

1      **Claim 16. (new)** A classification and management system for patients with  
2      lower extremity arterial occlusive disease comprising the steps of:

- 3          • examining a patient at a healthcare facility with lower extremity arterial  
4          occlusion disease,
- 5          • collecting patient data including patient diagnoses, pertinent physical  
6          findings and noninvasive arterial pressure and blood flow data,
- 7          • recording the collected patient data,
- 8          • transmitting said collected patient data to an evaluating authority,
- 9          • comparing said collected patient data against a medically accepted set  
10         of disease specific criteria at the evaluating authority to provide an initial  
11         diagnosis and preliminary classification of those patients “potentially at  
12         risk” and those patients “not at risk” of developing complications of  
13         arterial occlusive disease,
- 14         • transmitting said preliminary classification to the healthcare facility,
- 15         • referring those patients classified as “potentially at risk” of arterial  
16         occlusive disease to an accredited laboratory for noninvasive vascular  
17         evaluation,
- 18         • evaluating those “potentially at risk” patients at the accredited  
19         laboratory against medically accepted criteria,
- 20         • recording the results of said noninvasive vascular evaluation at the  
21         accredited laboratory,
- 22         • transmitting said recorded results to the evaluating authority for final  
23         classification,
- 24         • classifying each patient at the evaluating authority against medically  
25         accepted criteria as “at risk” or “not at risk”,
- 26         • transmitting said “at risk” or “not at risk” patient final classification to the  
27         healthcare facility,
- 28         • recording said “at risk” or “not at risk” patient final classification at the  
29         healthcare facility,
- 30         • referring patients having a final classification of “at risk” for critical  
31         ischemia with associated extremity lesions and patients with  
32         noninvasive evidence of severe ischemia to a vascular surgery facility

33 for vascular surgical assessment to determine whether  
34 revascularization is necessary,

35 • assessing such “at risk” patients against medically accepted criteria as  
36 “clinical indication for operation” or “no indication for operation” at the  
37 vascular surgery facility,

38 • transmitting patient assessments assessed as “clinical indication for  
39 operation” or “no indication for operation” assessment to the evaluating  
40 authority,

41 • informing those patients assessed as “clinical indication for operation”,

42 • electing either revascularization and periodic management system  
43 evaluation at the healthcare facility or routine wound care and periodic  
44 revaluation at the healthcare facility by patients assessed as “clinical  
45 indication for operation”,

46 • monitoring patients assessed as “no indication for operation” by the  
47 healthcare facility with increased precautions to monitor for detection of  
48 any deterioration that would require reassessment,

49 • referring patients having ulcers, pain or gangrene at the time of “no  
50 indication for operation” assessment for reassessment,

51 • recording the reasons for not referring such patients as “clinical  
52 indication for operation”,

53 • referring patients classified as “no indication for operation” that develop  
54 ulcers, pain and/or gangrene to the vascular surgery facility for  
55 reassessment,

56 • reassessing the referred patient at the vascular surgery facility against  
57 medically accepted criteria as “no indication for operation” or “clinical  
58 indication for operation”,

59 • transmitting the reassessment of “no indication for operation” or “clinical  
60 indication for operation” to the evaluating authority for reevaluation as  
61 “no indication for operation” or “clinical indication for operation”,

62 • transmitting the reevaluation to the healthcare faculty with the  
63 appropriate medical procedure and regimen,

64 • treating and monitoring patients classified as “not at risk”, “at risk” and  
65 assessed as “no indication for operation” or “clinical indication for  
66 operation” at the healthcare facility,

- 67       • providing “not at risk” patients without limb ulcers routine care and
- 68            precautions at the healthcare facility,
- 69        • providing “not at risk” patients with limb ulcers routine wound care at the
- 70            healthcare facility,
- 71        • providing “not at risk” patients with limb ulcers periodic reevaluation by
- 72            the evaluating authority,
- 73        • providing “at risk” patients assessed as “no indication for operation” or
- 74            “operation not elected by patient”, and “clinical indication for operation”
- 75            patient undergoing revascularization at the vascular surgery facility with
- 76            intensive wound care at the healthcare facility, and,
- 77        • providing periodic reevaluations of “at risk” patients assessed as “no
- 78            indication for operation” or “operation not elected by patient” with
- 79            increased precautions at the healthcare facility.